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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,302	12/09/2003	William F. Weitzel	UOM 0321 PUS	3644

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,302

Applicant(s)

WEITZEL ET AL

Examiner

Jaworski Francis J.

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Excised Specimen Case

Claims 1-2, 4, 7-8, 10, 12, 15, 25-26, 28, 31-32, 34, 36, 39, 41, 43, 46-47 insofar as they incorporate the limitations of cancelled claims 49-50, 52-54 are again rejected

Art Unit: 3737

under 35 U.S.C. 102(b) as being anticipated by Langwouters et al (Jrnl Biomech. 1984 Vol. 17, of record with applicants' IDS filed March 22, 2004). Using the interpretation that base claim 1 is not limited to in-vivo methodology but extends to include an in vitro investigative method using physiologic pressure levels, the Langewouters et al Fig. 1 apparatus and protocol consists of altering pressures by reducing or increasing wrt normal ranges across the specimen arterial wall, measuring intramural diameter displacement deformation and determining features of the mechanical compliance curve from the results. Since Langewouters et al apply supranormal intra-arterial pressures in the Fig. 3 measurement cycle they necessarily are measuring over a pressure range (supranormal) having a larger pressure-strain relationship than the normal because of the inherent nature of the artery, and may step increment in either direction so as to provide mean or static pressures in a reducing sequence.

Claims 3, 11, 27, 33, 35, 42 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Langewouters et al as applied to claim 1 above, and further in view of Banks et al (Circulation 7/6/99, of record with the 3/22/04 IDS) or Sarvazyan et al (US5524636) since whereas the former elects to use an x-ray to derive baseline artery segment diameter (page 427 col. 1 bottom para) it would have been obvious in view of Banks et al page 42 brachial discussion or Sarvazyan et al col. 24 lines 31-45 to use ultrasound imaging since this was a known equivalent for producing artery diameter information.

.Claims 9, 16-19, 22-23, 40, 48 insofar as they incorporate the limitations of cancelled claim 51 are again rejected under 35 U.S.C. 103(a) as being unpatentable

Art Unit: 3737

over Langewouters et al as applied to claim 1 above, and further in view of Breul et al (Atherosclerosis 127 (1996) of record in the IDS) since the page 156 Fig.1 graph therein shows that aortic stiffness hence inverse compliance may derive directly from a load-strain curve in the in vitro case. Further, since Bruel et al relate the arterial stiffness associated with aging as commented upon by the former to susceptibility to atherosclerosis, this is an index of how 'disease prone' an arterial segment would be and its health (suppleness) although excised from the body at autopsy.

II. In-Vivo Measurements

Claims 1-6, 8-14,16-21,23-30,32-38, 40-45 and 47-48 and insofar as they incorporate the limitations of cancelled claims 49 - 54 are again rejected under 35 U.S.C. 103(a) as obvious over the combined teachings of Banks et al (see entire article) and Sarvazyan et al (see col. 20 line 3 –col. 24 line 45 with additional note that since the static applied pressure is varied across normal physiologic ranges one necessarily applies first and second mean arterial pressures with differing pressure-strain slopes.) For simplicity these analogous applied cuff pressure measurement systems are grouped together – Banks et al is more attentive to the transmural pressure vs displacement relationships; Sarvazyan et al overtly mentions the direct computation of vessel wall strains from the cuff system configuration, see col. 21 lines 6-15.

Response to Arguments

Applicants' comments have been carefully considered, however a review of the definition of *intramural* indicates (using Schmidt's Attorneys' Dictionary of Medicine,

Art Unit: 3737

Bender Publ. N.y. 1980) that the term means "...Occurring or arising within the substance of a wall or organ or structure, as an intramural tumor...". Therefore no flexible wall having a thickness can deform in any fashion without an intramural deformation, hence the term is substantially non-limiting relative to its absence in terms of ascribing the broadest reasonable interpretation to the claims, and the incorporation of the limitation into the base claims cannot serve to create patentability for otherwise rejectable subject matter.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

01072006



Francis J. Jaworski
Primary Examiner